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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/637,216 08/11/00 HULTGREN

S WSHU2005.1

000321 HM12/0508
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16TH FLOOR
ST LOUIS MO 63102

EXAMINER

SHEINBERG, M

ART UNIT

PAPER NUMBER

1631

DATE MAILED:

05/08/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/637,216

Applicant(s)

HULTGREN ET AL.

Examiner

Monika B. Sheinberg

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1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-135 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claims 1-135 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 August 2000 is/are objected to by the Examiner. (See PTO-948)
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____
- 18) ☐ Interview Summary (PTO-413) Paper No(s). ____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-21, drawn to an isolated compound classified in class 530, 536, subclass 300, 1.11 respectively. *(If this group is elected, please see Species Election A and B, further below).*
- II. Claims 22-26, drawn to a composition containing a mimic of an amino-terminal motif, classified in class 530, subclass 300. *(If this group is elected, please see Species Election A and B, further below).*
- III. Claims 27-33, drawn to a composition containing a mimic of a chaperone G₁ beta-strand, classified in class 530, subclass 300. *(If this group is elected, please see Species Election A and B, further below).*
- IV. Claims 34-38, drawn to method of preventing or inhibiting formation of a pilus subunit-subunit structure in a subject, classified in class 514, subclass 2. *(If this group is elected, please see Species Election B further below).*
- V. Claims 39-41, drawn to a method of preventing or inhibiting formation of a chaperone-subunit structure in a subject, classified in class 514, subclass 2. *(If this group is elected, please see Species Election B further below).*
- VI. Claim 42, drawn to a method of preventing or inhibiting pili adhesion, classified in class 514, subclass 2. *(If this group is elected, please see Species Election B further below).*

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- VII. Claims 43-49, drawn to a method of treating a bacterial infection using a peptide or peptide analog according to formula (I), classified in class 514, subclass 2. *(If this group is elected, please see Species Election B further below).*
- VIII. Claims 50-55, drawn to a method of treating a bacterial infection using a peptide or peptide analog according to formula (II), classified in class 514, subclass 2. *(If this group is elected, please see Species Election B further below).*
- IX. Claims 56-60, drawn to a method of preventing or inhibiting biofilm formation, classified in class 514, subclass 2. *(If this group is elected, please see Species Election A and B, further below).*
- X. Claims 61-65, drawn to a method for inhibiting bacterial colonization, classified in class 435, subclass 245. *(If this group is elected, please see Species Election A and B, further below).*
- XI. Claims 66-79, drawn to a composition comprising a pilus chaperone-subunit co-complex, classified in class 530, subclass 300.
- XII. Claim 80, drawn to a method of crystallization, classified in class 530, subclass 333.
- XIII. Claims 81-122, drawn to a method of identifying an antibacterial compound using three-dimensional representations, classified in class 395, subclass 500.05.
- XIV. Claim 123-135, drawn to a machine-readable medium, classified in class 395, subclass 500.23.

The inventions are distinct, each from the other because of the following reasons:

The following groupings of inventions are independent and distinct because Group I pertains to an isolated compound; Groups (II, III, and XI) pertain to different compositions; Groups (IV-X, and XII-XIII) pertain to various methods; and Group XIV pertains to a machine-readable medium.

The compositions of Groups (II, III, and XI) have varying critical features; the composition of Group II contains a mimic of an amino-terminal motif, the composition of Group III contains a mimic of a chaperone G₁ beta-strand; and the composition of Group XI contains a complex in crystalline form.

The methods of Groups (IV-X, and XII-XIII) have different critical actions; Group IV prevents or inhibits formation of a pilus subunit-subunit structure; Group V prevents or inhibits formation of a chaperone-subunit structure; Group VI prevents or inhibits pili adhesion; Group VII treats a bacterial infection using a peptide or peptide analog according to formula (I); Group VIII treats a bacterial infection using a peptide or peptide analog according to formula (II) ; Group IX prevents or inhibits biofilm formation; Group X inhibits bacterial colonization; Group XII is crystallization; and Group XIII identifies an antibacterial compound using three-dimensional representations.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Species Election A:

This application contains claims directed to the following patentably distinct macro-species of the claimed invention: (please note further sub-species per election)

(a) Peptide (b) Non-peptide

*******IF (a) Peptide** is elected then one of the following patentably distinct first sub-species of the claimed invention must be elected:

(c) Formula I:

$Z_1 \sim Z_2 - X_1 - X_2 - X_3 - X_4 - X_5 - X_6 - X_7 - X_8 - X_9 - X_{10} - Z_3 \sim Z_4$

(d) Formula II:

$Z_{11} \sim Z_{12} - X_{11} - X_{12} - X_{13} - X_{14} - X_{15} - X_{16} - X_{17} - Z_{13} \sim Z_{14}$

****Upon** the election of one of the two formulas, ONE of the following corresponding SEQ ID No's must be elected:

SEQ ID No: 1	SEQ ID No: 2	SEQ ID No: 3	SEQ ID No: 4	SEQ ID No: 5
SEQ ID No: 6	SEQ ID No: 7	SEQ ID No: 8	SEQ ID No: 9	SEQ ID No: 10
SEQ ID No: 11	SEQ ID No: 12	SEQ ID No: 13	SEQ ID No: 14	SEQ ID No: 15
SEQ ID No: 16	SEQ ID No: 17	SEQ ID No: 18	SEQ ID No: 19	SEQ ID No: 20
SEQ ID No: 21	SEQ ID No: 22	SEQ ID No: 23	SEQ ID No: 24	SEQ ID No: 25
SEQ ID No: 26	SEQ ID No: 27	SEQ ID No: 28	SEQ ID No: 29	SEQ ID No: 30
SEQ ID No: 31	SEQ ID No: 32	SEQ ID No: 33	SEQ ID No: 34	SEQ ID No: 35
SEQ ID No: 36	SEQ ID No: 37	SEQ ID No: 38	SEQ ID No: 39	SEQ ID No: 40
SEQ ID No: 41	SEQ ID No: 42	SEQ ID No: 43	SEQ ID No: 44	SEQ ID No: 45
SEQ ID No: 46	SEQ ID No: 47	SEQ ID No: 48	SEQ ID No: 49	SEQ ID No: 50
SEQ ID No: 51	SEQ ID No: 52			

*******IF (a) Non-Peptide** is elected then one of the following patentably distinct first sub-species of the claimed invention must be elected:

(e) Mannose analogue

(f) Non-mannose type materials

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 1 is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Species Election B:

No claim found generic. All the below were listed in the following claims alike: 7, 10, 15, 19, 21, 47, and 53. The following are the species:

(a) *Escherichia coli*,

(f) *Yersinia perstis*,

- | | |
|-------------------------------------|--------------------------------------|
| (b) <i>Haemophilus influenzae</i> , | (g) <i>Yersinia enterocolitica</i> , |
| (c) <i>Salmonella enteritidis</i> , | (h) <i>Helicobacter pylori</i> , and |
| (d) <i>Salmonella typhimurium</i> , | (i) <i>Klebsiella pneumoniae</i> . |
| (e) <i>Bordetella pertussis</i> , | |

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the

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Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242, or (703) 308-4028.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Monika B. Sheinberg, whose telephone number is (703) 306-0511. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Patent Analyst, Tina Plunkett, whose telephone number is (703) 305-3524, or to the Technical Center receptionist whose telephone number is (703) 308-0196.

May 6, 2001

Monika B. Sheinberg
Patent Examiner
Art Unit 1631

MBS

Ardin H. Marschel
ARDIN H. MARSCHEL
PRIMARY EXAMINER